DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0969]

Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals (GFI #78); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled "Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals" (GFI #78). After the agency considered public comments on a draft of this guidance, announced in the **Federal Register** of November 18, 1998, it determined that revision of the draft guidance was necessary. GFI #78 addresses how under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) FDA intends to consider the potential human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs. For additional information regarding the subject matter dealt with in GFI #78, see the notice of availability of the document entitled "FDA Response to Comments on a Proposed Framework for Evaluating and Assuring the Human Food Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals" that appears elsewhere in this issue of the **Federal Register.**

DATES: Submit comments at any time.

ADDRESSES: Submit written comments on GFI #78 to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852.

FDA will also accept electronic comments. Persons who wish to submit electronic comments should go to the FDA home page at www.fda.gov and select "Dockets" and follow the instructions.

Submit written requests for single copies of the document entitled "Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals" (GFI #78) to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See section **III. Electronic Access** of this document for information on electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sharon Thompson, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1798, e-mail: sthompso@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 18, 1998 (63 FR 64094), FDA announced the availability of a draft guidance entitled "Guidance for Industry: Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals" (GFI #78). This draft guidance announced that FDA believed that it is necessary to evaluate the human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs. The publication of the draft of GFI #78 was the first step in the agency's consideration of the issues related to the use of antimicrobial new animal drugs in food-producing animals. The draft of GFI #78 laid out the agency's rationale for its current thinking about its

authority under section 512 of the act to consider the human health impact of the microbial effects associated with the use of antimicrobial new animal drugs in food-producing animals.

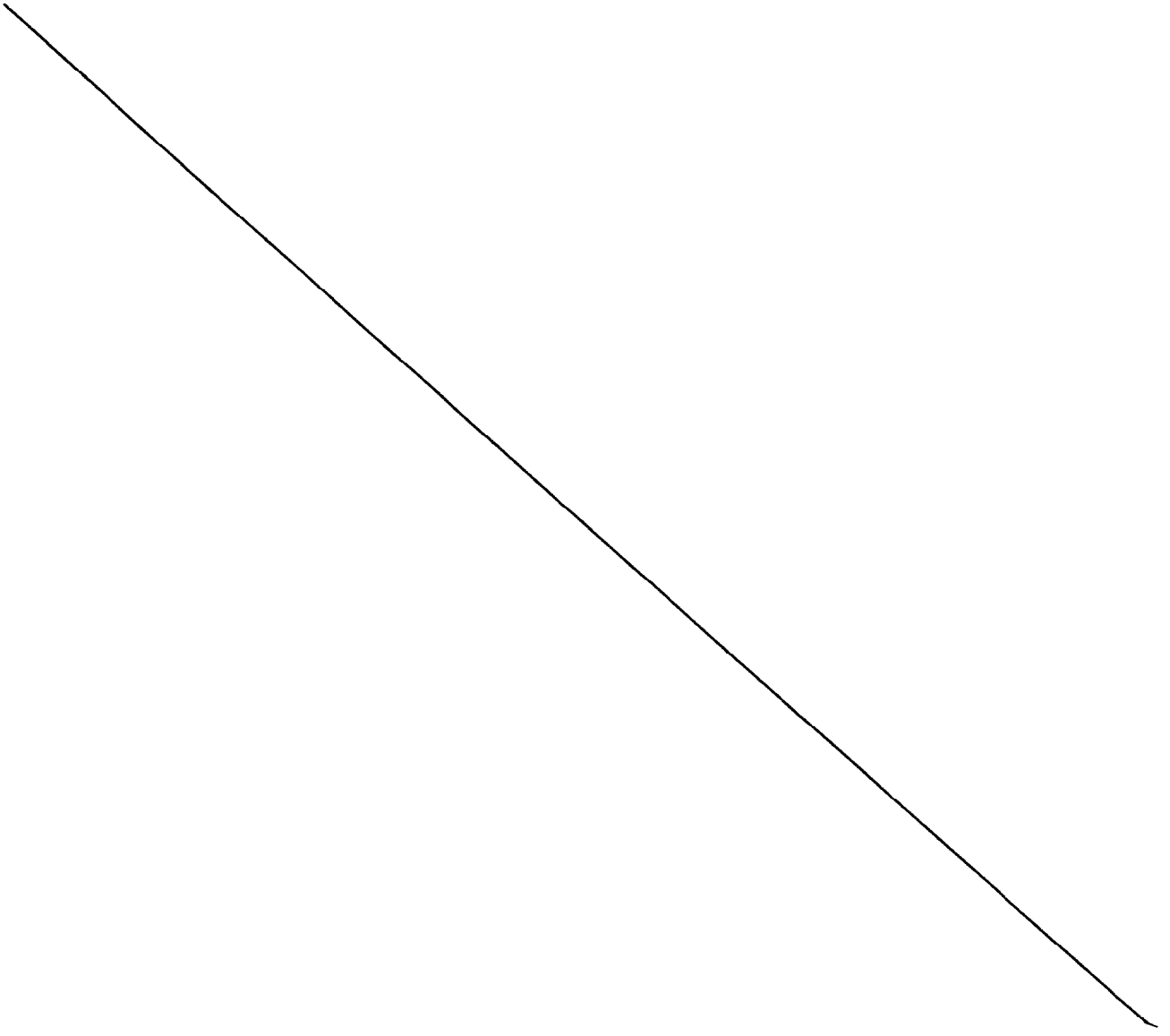
In the **Federal Register** of January 6, 1999 (64 FR 887), FDA announced the availability of a discussion paper entitled "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals" (Framework Document). The Framework Document was the second step in the agency's consideration of issues related to the use of antimicrobial new animal drugs in food-producing animals. FDA made the Framework Document available to the public to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying concepts to be used to develop microbial safety policies protective of the public health. The Framework Document is related to GFI #78 in that it sets out a conceptual risk-based framework for evaluating the microbial safety (related to human health impact) of antimicrobial new animal drugs intended for use in food-producing animals.

After considering comments received by the public for both the draft of GFI #78 and the Framework Document, FDA determined that it was necessary to make some revisions to GFI #78. The revisions are intended to make GFI #78 more clearly reflect the agency's intentions regarding this issue. For example, the words "evaluate" and "evaluation" have been changed to "consider" and "consideration," and other changes have been made to indicate that additional testing would not always be needed to determine the potential human health impact of the microbial effects associated with antimicrobial new animal drugs intended for use in food-producing animals.

GFI #78 represents the agency's current thinking on how under section 512 of the act it intends to consider the potential human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs. It does not create or confer any right for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Comments

Interested persons may, at any time, submit written or electronic comments on GFI #78 to the Dockets Management Branch (address above). Two copies of written comments are to be submitted, except that individuals may submit one copy. All comments are to be identified with the docket number found in brackets in the heading of this document. GFI #78 and written and electronic comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain copies of "Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals" (GFI #78) at http://www.fda.gov/cvm.

Dated: December 8, 1999

Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 99–???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F